

**UNITED STATES DISTRICT COURT  
DISTRICT OF DELAWARE**

THE TRUSTEES OF COLUMBIA  
UNIVERSITY IN THE CITY OF NEW YORK  
and QIAGEN SCIENCES, LLC,

Plaintiffs,

v.

ILLUMINA, INC.,

Defendant.

C.A. No. 19-1681-CFC

**JURY TRIAL DEMANDED**

**ANSWER**

Defendant Illumina, Inc. (“Illumina” or “Defendant”), by and through its undersigned counsel, hereby answers the Amended Complaint (D.I. 12) (“First Amended Complaint”) filed by Plaintiffs The Trustees Of Columbia University In The City Of New York (“Columbia”) and Qiagen Sciences, LLC (“Qiagen”) (collectively, “Plaintiffs”) by admitting, denying, and alleging as follows:

**THE PARTIES**

1. Illumina admits, upon information and belief, that Columbia is an institution of higher education, located at 535 West 116th Street. New York, New York 10027, and is a non-profit educational corporation formed by special act of the Legislature of the State of New York.

2. Illumina admits, upon information and belief, that Qiagen is a Delaware company with its principal place of business at 19300 Germantown Road, Germantown, MD 20874. Illumina is without sufficient knowledge to admit or deny the remaining allegations of this paragraph, and on that basis denies them.

3. Illumina admits that it is a Delaware corporation with its principal place of business at 5200 Illumina Way, San Diego, California 92122.

### **JURISDICTION AND VENUE**

4. Illumina admits that the First Amended Complaint purports to state an action arising under the Patent Laws of the United States of America, 35 U.S.C. § § 1 *et seq.*, but denies the viability of such action.

5. Illumina admits that the First Amended Complaint alleges federal question subject matter jurisdiction over this action, but denies the viability of such action.

6. Illumina admits that this Court has personal jurisdiction over Illumina.

7. Illumina admits that Venue is proper in this judicial district.

### **BACKGROUND**

#### **The Patents-in-Suit**

8. Illumina admits, upon information and belief, that on September 10, 2019, the United States Patent and Trademark Office issued U.S. Patent No. 10,407,458 (the “458 Patent”), entitled “Massive Parallel Method for Decoding DNA and RNA,” in the names of Jingyue Ju, Zengmin Li, John Robert Edwards, and Yasuhiro Itagaki. Except as so admitted, denied.

9. Illumina admits, upon information and belief, that on September 10, 2019, the United States Patent and Trademark Office issued U.S. Patent No. 10,407,459 (the “459 Patent”), entitled “Massive Parallel Method for Decoding DNA and RNA,” in the names of Jingyue Ju, Zengmin Li, John Robert Edwards, and Yasuhiro Itagaki. Except as so admitted, denied.

10. Illumina admits, upon information and belief, that on October 1, 2019, the United States Patent and Trademark Office issued U.S. Patent No. 10,428,380 (the “’380 Patent”), entitled “Massive Parallel Method for Decoding DNA and RNA,” in the names of Jingyue Ju, Zengmin Li, John Robert Edwards, and Yasuhiro Itagaki. Except as so admitted, denied.

11. Illumina admits, upon information and belief, that on October 8, 2019, the United States Patent and Trademark Office issued U.S. Patent No. 10,435,742 (the “’742 Patent”), entitled “Massive Parallel Method for Decoding DNA and RNA,” in the names of Jingyue Ju, Zengmin Li, John Robert Edwards, and Yasuhiro Itagaki. Except as so admitted, denied.

12. Illumina admits, upon information and belief, that on October 29, 2019, the United States Patent and Trademark Office issued U.S. Patent No. 10,457,984 (the “’984 Patent”) (collectively with the ’458 Patent, ’459 Patent, ’380 Patent, and ’742 Patent, the “Patents-in-Suit”) entitled “Massive Parallel Method for Decoding DNA and RNA,” in the names of Jingyue Ju, Zengmin Li, John Robert Edwards, and Yasuhiro Itagaki. Except as so admitted, denied.

13. Illumina is without knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 13, and therefore denies those allegations.

14. Illumina is without knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 14, and therefore denies those allegations.

15. Illumina admits, upon information and belief, that on January 31, 2019, the applications that issued as the ’458 Patent, the ’380 Patent, and the ’742 Patent published as US2019/0031704, US2019/0031705, and US2019/0031706, respectively.

16. Illumina admits, upon information and belief, that on March 21, 2019, the applications that issued as the ’459 Patent and ’984 Patent published as US2019/0085014 and

US2019/0085015 (collectively with US2019/0031704, US2019/0031705, and US2019/0031706, the “Published Applications”), respectively.

17. Illumina denies the allegation of paragraph 17.

18. Illumina admits that it has been a party to patent litigation with Columbia and Qiagen. Illumina further admits that it became aware of the Patents-in-Suit after their issuance, but denies that it monitors all patents involving DNA sequencing technology. Except as so admitted, Illumina denies the allegations of paragraph 18.

**Nucleotides and DNA Sequencing**

19. Illumina admits, upon information and belief, the allegations of paragraph 19.

20. Illumina admits, upon information and belief, the allegations of paragraph 20.

21. Illumina admits, upon information and belief, the allegations of paragraph 21.

22. Illumina admits, upon information and belief, the allegations of paragraph 22.

23. Illumina admits, upon information and belief, the allegations of paragraph 23.

24. Illumina admits, upon information and belief, the allegations of paragraph 24.

**Columbia University’s Patents-in-Suit**

25. Illumina admits that the allegations in Paragraph 25 generally describe aspects of next generation sequencing (“NGS”). Except as so admitted, denied.

26. Illumina admits that the allegations in Paragraph 26 generally describe aspects of sequencing by synthesis (“SBS”). Except as so admitted, denied.

27. Illumina admits that the allegations in Paragraph 27 purport to describe the teachings of the Patents-in-Suit. Except as so admitted, denied.

28. Illumina admits that the allegations in Paragraph 28 purport to describe the teachings of the Patents-in-Suit. Except as so admitted, denied.

29. Illumina admits, upon information and belief, that paragraph 29 of the First Amended Complaint quotes claim 1 of the ’459 Patent.

**Illumina Makes, Uses, and Sells Nucleotide Analogues That Are Alleged To Infringe The Patents-in-Suit**

30. Illumina admits that it manufactures, uses, imports, and/or sells DNA sequencing instruments in the United States, including the instruments listed in paragraph 30 of the First Amended Complaint. Except as so admitted, Illumina denies the allegations in paragraph 30 of the First Amended Complaint.

31. Illumina admits that it (now or in the past) manufactures, uses, imports, and/or sells reagent kits in the United States, including the kits listed in paragraph 31 of the First Amended Complaint. Except as so admitted, Illumina denies the allegations in paragraph 31 of the First Amended Complaint.

32. Illumina admits that it offers DNA services. Except as so admitted, Illumina denies the allegations in paragraph 32 of the First Amended Complaint.

33. Illumina admits that authors from Illumina and others published an article in *Nature* titled “Accurate Whole Human Genome Sequencing using Reversible Terminator Chemistry” (the “Bentley article”) and that *Nature* also published “Supplementary Information” that relates to the Bentley article.

34. Illumina admits that the Bentley article speaks for itself. Except as so admitted, denied.

35. Illumina admits that the Bentley article speaks for itself. Except as so admitted, denied.

36. Illumina admits that Illumina CMOS Chip and One-Channel SBS Chemistry speaks for itself. Except as so admitted, denied.

37. Illumina admits that Illumina CMOS Chip and One-Channel SBS Chemistry speaks for itself. Except as so admitted, denied.

38. Denied as stated. The First Amended Complaint seeks to impose obligations that go far beyond what the Federal Rules of Civil Procedure and this district's Local Rules contemplate or allow, and Illumina denies on that basis. To the extent that Plaintiffs seek to incorporate each element of the claim chart as an allegation, the allegations do not comply with Federal Rule of Civil Procedure 8(d) that requires that "each allegation must be simple, concise, and direct." For example, some allegations span pages of text. Moreover, the allegations are vague and ambiguous as Plaintiffs have indicated that the claim chart is "preliminary and exemplary" and that they have "the right to modify the chart." Therefore, Illumina denies the allegations on these bases as well.

39. Paragraph 39 is legal argument and no response is required beyond what is set forth in response to paragraph 38. On that basis, denied.

40. Illumina denies the allegations in paragraph 40.

**COUNT I**

**Alleged Infringement of U.S. Patent No. 10,407,458**

41. Illumina re-asserts and incorporates by reference the answers provided in paragraphs 1-40 above, in response to the allegations contained in paragraphs 1-40.

42. Illumina denies the allegations in paragraph 42.

43. Illumina denies the allegations in paragraph 43.

44. Illumina denies the allegations in paragraph 44.

45. Illumina denies the allegations in paragraph 45.

46. Illumina admits that it has been a party to patent litigation and *inter partes* proceedings with Columbia and Qiagen and it is aware of the asserted patents. Except as so admitted, Illumina denies the allegations in paragraph 46 of the First Amended Complaint.

47. Illumina denies the allegations in paragraph 47 of the First Amended Complaint, and specifically denies that Columbia and/or Qiagen are entitled to the relief they seek.

**COUNT II**

**Alleged Infringement of U.S. Patent No. 10,407,459**

48. Illumina re-asserts and incorporates by reference the answers provided in paragraphs 1-47 above, in response to the allegations contained in paragraphs 1-47.

49. Illumina denies the allegations in paragraph 49.

50. Illumina denies the allegations in paragraph 50.

51. Illumina denies the allegations in paragraph 51.

52. Illumina denies the allegations in paragraph 52.

53. Illumina admits that it has been a party to patent litigation and *inter partes* proceedings with Columbia and Qiagen and it is aware of the asserted patents. Except as so admitted, Illumina denies the allegations in paragraph 53 of the First Amended Complaint.

54. Illumina denies the allegations in paragraph 54 of the First Amended Complaint, and specifically denies that Columbia and/or Qiagen are entitled to the relief they seek.

### **COUNT III**

#### **Alleged Infringement of U.S. Patent No. 10,428,380**

55. Illumina re-asserts and incorporates by reference the answers provided in paragraphs 1-54 above, in response to the allegations contained in paragraphs 1-54.

56. Illumina denies the allegations in paragraph 56.

57. Illumina denies the allegations in paragraph 57.

58. Illumina denies the allegations in paragraph 58.

59. Illumina denies the allegations in paragraph 59.

60. Illumina admits that it has been a party to patent litigation and *inter partes* proceedings with Columbia and Qiagen and it is aware of the asserted patents. Except as so admitted, Illumina denies the allegations in paragraph 60 of the First Amended Complaint.

61. Illumina denies the allegations in paragraph 61 of the First Amended Complaint, and specifically denies that Columbia and/or Qiagen are entitled to the relief they seek.

### **COUNT IV**

#### **Alleged Infringement of U.S. Patent No. 10,435,742**

62. Illumina re-asserts and incorporates by reference the answers provided in paragraphs 1-61 above, in response to the allegations contained in paragraphs 1-61.

63. Illumina denies the allegations in paragraph 63.



64. Illumina denies the allegations in paragraph 64.

65. Illumina denies the allegations in paragraph 65.

66. Illumina denies the allegations in paragraph 66.

67. Illumina admits that it has been a party to patent litigation and *inter partes* proceedings with Columbia and Qiagen and it is aware of the asserted patents. Except as so admitted, Illumina denies the allegations in paragraph 67 of the First Amended Complaint.

68. Illumina denies the allegations in paragraph 68 of the First Amended Complaint, and specifically denies that Columbia and/or Qiagen are entitled to the relief they seek.

### **COUNT V**

#### **Alleged Infringement of U.S. Patent No. 10,457,984**

69. Illumina re-asserts and incorporates by reference the answers provided in paragraphs 1-68 above, in response to the allegations contained in paragraphs 1-68.

70. Illumina denies the allegations in paragraph 70.

71. Illumina denies the allegations in paragraph 71.

72. Illumina denies the allegations in paragraph 72.

73. Illumina denies the allegations in paragraph 73.

74. Illumina admits that it has been a party to patent litigation and *inter partes* proceedings with Columbia and Qiagen and it is aware of the asserted patents. Except as so admitted, Illumina denies the allegations in paragraph 74 of the First Amended Complaint.

75. Illumina denies the allegations in paragraph 75 of the First Amended Complaint, and specifically denies that Columbia and/or Qiagen are entitled to the relief they seek.

### **RESPONSE TO PRAYER FOR RELIEF**

76. Illumina denies that Columbia or Qiagen is entitled to any relief whatsoever, including the relief requested in paragraphs A to F of the Prayer for Relief of the First Amended Complaint, from Illumina or the Court, either as prayed for in the First Amended Complaint or otherwise.

### **GENERAL DENIAL**

77. Illumina further denies each and every allegation in the First Amended Complaint that is not specifically admitted, denied or otherwise responded to in this Answer.

### **DEFENSES**

#### **First Defense (Failure to State a Claim)**

78. The First Amended Complaint fails to state a claim upon which relief can be granted.

#### **Second Defense (Noninfringement)**

79. Illumina has not infringed and does not infringe, either directly, indirectly, contributorily, by inducement, or in any other manner, either literally or under the doctrine of equivalents, any valid or enforceable claim of the Patents-in-Suit.

#### **Third Defense (Invalidity)**

80. One or more of the claims of the Patents-in-Suit are invalid for failure to comply with one or more of the requisite statutory and decisional requirements and/or conditions for patentability under Title 35 of the United States Code, including without limitation those set forth in one or more of 35 U.S.C. §§ 102, 103, and/or 112.

**Fourth Defense (Estoppel)**

81. Columbia and Qiagen's claims are barred in whole or in part by the doctrines of estoppel, disclaimer, and/or waiver.

**Fifth Defense (Limitation of Damages)**

82. Any potential damages recovery is barred in whole or in part by 35 U.S.C. §§ 286, 287, and/or 288.

**Sixth Defense (Claim and/or Issue Preclusion)**

83. Columbia and Qiagen's claims are barred in whole or in part by the doctrines of claim and/or issue preclusion based on but not limited to at least the following proceedings: *The Trustees of Columbia University in the City of New York v. Illumina, Inc.*, C.A. No. 12-376-GMS (D. Del.); IPR2012-00006; IPR2012-00007; IPR2013-00011; *The Trustees of Columbia University in the City of New York v. Illumina, Inc.*, No. 2014-1547 (Fed. Cir.); *The Trustees of Columbia University in the City of New York v. Illumina, Inc.*, No. 2014-1548 (Fed. Cir.); *The Trustees of Columbia University in the City of New York v. Illumina, Inc.*, No. 2014-1550 (Fed. Cir.); *The Trustees of Columbia University in the City of New York v. Illumina, Inc.*, 620 Fed. Appx. 916 (Fed. Cir. 2015); *The Trustees of Columbia University in the City of New York v. Illumina, Inc.*, C.A. No. 17-973-UNA (D. Del.); IPR2018-00291; IPR2018-00318; IPR2018-00322; IPR2018-00385; IPR2018-00797; *The Trustees of Columbia University in the City of New York v. Illumina, Inc.*, No. 2019-2302 (Fed. Cir.); *The Trustees of Columbia University in the City of New York v. Illumina, Inc.*, No. 2019-2303 (Fed. Cir.); *The Trustees of Columbia University in the City of New York v. Illumina, Inc.*, No. 2019-2304 (Fed. Cir.); and/or *The Trustees of Columbia University in the City of New York v. Illumina, Inc.*, No. 2019-2305 (Fed. Cir.).

**Seventh Defense**

84. Illumina reserves the right to plead other defenses that might arise during this course of litigation.

Respectfully submitted,

ASHBY & GEDDES

*/s/ Steven J. Balick*

Of Counsel:  
Edward R. Reines  
Derek C. Walter  
WEIL, GOTSHAL & MANGES LLP  
Silicon Valley Office  
201 Redwood Shores Parkway  
Redwood Shores, CA 94065  
(650) 802-3000  
edward.reines@weil.com  
derek.walter@weil.com

---

Steven J. Balick (#2114)  
Andrew C. Mayo (#5207)  
500 Delaware Avenue, 8th Floor  
P.O. Box 1150  
Wilmington, DE 19899  
(302) 654-1888  
sbalick@ashbygeddes.com  
amayo@ashbygeddes.com

*Attorneys for Defendant*

Dated: November 12, 2019